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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,782	08/13/2001	Robert O. Ralston	154.206	1144

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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 07/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,782

Applicant(s)

RALSTON ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20- 23 and 44- 79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20- 23 and 44- 79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to Request for Reconsideration filed 1 March 2002. The following claims are being considered in this action: 20- 23 and 44- 79. Claims 1- 19 and 24- 43 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20- 23 and 44- 79 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "specific" in the phrase "antibody specific for said hepatitis c virus (HCV) glycoprotein" is a relative term which renders the claim indefinite.

The rejection of record is maintained

Applicant argues that one of skill in the art would certainly recognize an antibody as specific and that relative terms do not automatically render a claim indefinite. Applicant's argument is not found persuasive. One of skill in the art would recognize as specific an antibody if some property was demonstrated that showed specificity. It is not clear what the specificity of this antibody is and it is not clear in this recitation. Does this antibody react only with $\leq 10\%$ N-linked sialic acid but not with more than 10% sialic

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acid.⁷ Does the antibody react with only asialoglycoproteins and not with naked proteins?

Thus not knowing the specificity, the claim is not clear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20- 23, and 44- 79 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antigen production, does not reasonably provide enablement for specific antibodies and were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for concept of using an antigen to make an antibody, does not reasonably provide enablement for making an antibody "specific for" the stated antigen. Since it is not clear how specific is defined, one cannot produce "specific" antibodies without any understanding of what "specificity" is required.

The rejection of record is maintained.

Applicant argues that the proteins are described in detail and determining binding constants of antibodies are known in the art. Applicant's argument is not found persuasive because it is not clear how to make an antibody that does not recognize a particular epitope because antibodies usually recognize the presence of a particular structure and not the absence of a particular structure. Furthermore, Applicant states "discrimination is relative rather than absolute as antibodies cross react with a partially related antigen [and] affinity for partially related antigen would likely be less (Page 5,

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lines 20 and 22). This statement makes it less clear what the specificity really is because this allows for cross reactivity with other proteins and reactivity with related antigens would **likely** be less but it is not known how much less or at what point these factors restrict specificity.

Claims 20- 23, and 44- 79 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection of record is maintained.

Applicant argues that the original claims provide support and the specification need not teach what is known in the art. Applicant's argument is not found persuasive. The "antibody specific" is supported by the original claim 20, line 5 (now amended to be "isolated antibody specific"). The specification does not contemplate all the antibodies recited in the claims as they now stand. Furthermore, the Disclosure of the Invention (pages 3 and 4) does not mention antibodies. The level of skill in the art of antibodies was high at the time of filing; however, the specification contains no reference to physical properties or structure of the antibody nor does it teach antibodies specifically binding to E1 or E2.

Conclusion

All claims remain rejected.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800 1600